

## **REMARKS**

### **Claims**

Claims 54–56, 59–65, 68–70, 73 and 74 are currently under examination with claims 1–53, 57, 58, 66, 67, 71, 72, 75 and 76 cancelled without prejudice or disclaimer.

Claims 77–81 are added by this paper.

### **Claim amendments**

The claims have been amended in accordance with conventional US practice and to eliminate typographical errors.

The subject matter of claims 57–58 is now incorporated into amended claim 54. The subject matter of claims 66–67 is now incorporated into amended claim 65. The claims have been amended to establish proper dependencies. The subject matter in multiple dependent claims 56 and 73 are now recited in single dependent claims.

It is respectfully submitted that the claim amendments do not add new matter.

### **Specification**

The ABSTRACT has been amended as per the Examiner's suggestion. Withdrawal of the objection is respectfully requested.

### **Claim objections**

Applicants appreciate the Examiner's careful reading of the claims. The objections are moot in view of the amendments.

### **Rejections under 35 U.S.C. §101 and §112, second paragraph**

In item 9, the Office Action alleges that the recitation of the genes without proper recitation of the microorganism from which it is derived constitutes indefiniteness. Applicants respectfully disagree with this contention. It is submitted that each of the specified genes leads to the expression of an enzyme which has a specific function. As disclosed in Applicants' instant disclosure, the function of the claimed genes and the enzymes encoded by such genes are fully recognized in the art. See, page 2, 1<sup>st</sup> paragraph to page 3, 3<sup>rd</sup> paragraph of the specification and the disclosure contained in the Examples. Therefore it is not necessary to recite the microorganism from which the claimed gene is derived. One skilled in the art would recognize what genes are defined

by ascribing to the function of said genes and/or a product thereof. The specification provides embodiments for the construction, isolation and purification of appropriate vectors comprising said genes derived from a variety of microbial species. A skilled worker would recognize that the genes defined in the claims are not restricted to a particular organism. The Examiner is therefore respectfully requested to withdraw the pending rejection.

The rejection of claims 55, 63 and 65, not specifically discussed herein, are moot in view of the amendments. Withdrawal of the rejection is courteously requested.

**Rejection under 35 U.S.C. §112, first paragraph (enablement)**

Claims 63–67 stand rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

It is respectfully submitted that the specification provides adequate guidance regarding the plasmid vectors and/or the yeast strain claimed herein. More specifically, the specification discloses that the plasmid vectors species comprising one or more genes recited in Applicants' claim 54 can be obtained using techniques that are routinely available to one of ordinary skill in the art. Method for constructing the claimed plasmid vectors are provided in pages 20–21 of the instant specification. Restriction sites and maps of the claimed vectors are also provided. See, for example, Figs. 1–3 of the specification.

The specification also provides adequate guidance on the Yeast strain AH22 and methods for generating transformants comprising one or more claimed genes. See, for example, pages 22–24 of the instant specification. Methods for co-transforming microorganisms with one or more plasmid strains are also disclosed. See, pages 24–26 of the instant specification.

The cited reference of Basson et al., Fegueur et al., Yu et al., Jandrositz et al., which are recited in Applicants' instant specification, provide detailed disclosure on the genes involved in ergosterol metabolism. The specification, for example, the disclosure in Example 1, provides a detailed description of the plasmid constructs comprising said genes and methods for transforming a suitable host cell. As such, it is courteously submitted that the structural aspects of the plasmid species recited herein and the

genes encoded by such were fully disclosed by the combined disclosure of Applicants' instant specification and the references cited therein.

It is further submitted that the discipline, on which Applicants' instant invention is based, was mature prior to the filing of the instant application. For instance, a cursory search reveals that YEpH2, YDpUHK3, pADL-SAT1, and YEp13 are widely recognized in the art of microbiology. The specification provides adequate guidance on the state of the art prior on ergosterol metabolic genes prior to the filing of the instant application. See, pages 2–4 of the specification. Moreover, a search on Journal of Biological Chemistry with *S. cerevisiae* AH22 revealed more than 20 scientific publications prior to the earliest priority date of the instant application. A parallel search in PUBMED with the search term "Yeast strain AH22" revealed more than 20 publications. See enclosed Exhibits.

It is therefore submitted that the specification, further in view of the references cited therein, provides adequate guidance on the structure of claimed plasmid vectors and/or the microbe strains. Expressed written description of their exact structure is not required since such was readily available an average skilled worker prior to the filing of the instant application. The specification need not disclose, and preferably omits, what is well known to those skilled in the art. See, e.g., *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987). See, also, MPEP §2164.05(a). Indeed, the Federal Circuit found that an application, which failed to disclose the amino acid sequence of a claimed protein, was not deficient in the written description requirement, despite the fact that the undisclosed sequence was an essential part of the protein's description. See, *Capon v. Eshhar v. Dudas*, (Fed. Cir. 2005) 418 F.3d 1349, 76 U.S.P.Q.2d 1078. Likewise, in the instant application, the specification need not provide expressed guidance on the structural features of the claimed plasmid species, as such were not only known, but also commercially available to a skilled worker before the application was filed.

Utilizing routine techniques of molecular biology, a skilled worker could obtain the claimed compounds by, for example, constructing the claimed vectors, expressing in a suitable host cell, and purifying the claimed plasmid vectors comprising one or more genes of the ergosterol metabolic pathway. Not only is this routine but also explained in detail by the disclosure contained in Applicants' instant specification. The specification


also provides adequate guidance regarding the methods for producing yeast strains that are commensurate with the scope of the instant invention. Methods for purifying, analyzing, and testing the microbiological products formed are also described. Using this disclosure, a skilled worker could routinely screen for scope of compounds (for example, plasmids, yeast strains etc.) that are commensurate with the claims. No more than routine experimentation would be necessary.

In view of the above remarks, it is respectfully submitted that Applicants' disclosure provides more than sufficient guidance to objectively enable one of ordinary skill in the art to make and use the claimed invention with an effort that is routine with in the art. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

In view of the above and attached, it is respectfully submitted that the claims are in condition for allowance.

No fees are believed to be due with this response; however, the Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,



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